

Certificate of Analysis (CoA) for induced Pluripotent Stem Cells

This product is for research only



ECACC Catalogue No: 66540612

| | | | |
|------------------------------|--|--------------------------------|---------------------|
| Cell Line Name | PFIZI027-A | Batch Number | M001 |
| Donor ID | OD021 | | |
| Disease Association | Dravet Syndrome | Phenotype of Donor | Affected |
| Tissue of Origin | PBMC (Erythroblast) | Sex | Female |
| Reprogramming Method | Non-integrating Sendai Virus (POU5F1, SOX2, KLF4, MYC) | | |
| Passage Number | Passage 12 | Cell number / vial | 1.7x10 ⁶ |
| Culture Matrix | Geltrex / Matrigel | Culture Medium | mTeSR™1 |
| O ₂ Concentration | 20% | CO ₂ Concentration | 5% |
| Passaging Method | EDTA | Additional Culture Information | N/A |
| Cryopreservation Medium | 40% FBS* / 50% medium / 10% DMSO *Serum of Zone 1 origin | | |
| Recommendation for thawing | Recommended thaw into 2 wells of a 6-well plate or per 10cm ² Refer to cell line user protocols for further guidance at www.EBiSC.org | | |
| Additional Comments | Typical recovery after thaw, typical growth to confluency | | |
| Associated Publications | N/A | | |

Please see www.EBiSC.org for further information on Quality Control applied to lines released by EBiSC. The following standard testing criteria have been determined within EBiSC, prior to release of this product:

| Test | Assay | Acceptance Criteria | Result |
|---------------------------|--|--------------------------------|---|
| Sterility | Inoculation for microbiological growth | Not Detected | Pass |
| | qPCR for Mycoplasma | Not Detected | Pass |
| | Virology (HBV, HCV, HIV1, HIV2) | Not Detected | Pass |
| Cell Line Identity | Short Tandem Repeat analysis using PCR | N/A | Allele data recorded and available upon request. Profile match to donor |
| Viability | Visual Assessment | Growth to confluence post-thaw | Acceptable |
| Phenotype | Continuous visual assessment of iPSC colony morphology | Recorded | Typical iPSC colonies with low differentiation levels |



In case of queries, please contact culturecollections.technical@phe.gov.uk. European Collection of Authenticated Cell Cultures (ECACC), Culture Collections, Public Health England, Tel: +44 (0) 1980 612684

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| Test | Assay | Acceptance Criteria | Result |
|----------------------------------|--|--|---|
| Phenotype | Flow Cytometry | SSEA-4 > 70% + TRA-1-60 > 70% + SSEA-1 < 10% + POU5F1 > 70% + | Pass |
| Differentiation Potential | Spontaneous EB differentiation and qPCR for trilineage markers | Up-regulation of germ layer markers | Endoderm: Not detected Mesoderm: Detected Ectoderm : Detected |

Additional cell line characteristics have been determined by original reprogramming centres and have not been independently verified by EBiSC. Historical cell line data displayed here is accurate according to data provided by depositors on 23-OCT-2017

| Test | Assay | Result |
|---|--|---|
| Genetic Defect | Affymetrix 750K SNP Analysis | DCX gene deletion at Xq23 (coordinates 110,553,705 – 110,640,810) confirmed |
| Karyotype | G-banding 20 metaphase spreads | 16/20 diploid female karyotype (46,XX) 1/20 48,XX,+1,+11 1/20 46,XX,del(8)(p23) 1/20 45,XX,-12 1/20 44,XX,-19,-20 |
| | Affymetrix 750K SNP Analysis | Xq23 deletion only (DCX Deletion as expected) |
| Clearance of Reprogramming Factors | qPCR for Sendai Backbone | Not detected |
| Differentiation Potential | Directed differentiation and qPCR for endoderm markers | Endoderm: Detected |

The following guidance can be found in the Instructions for Use

| | |
|-----------------------|---------------------------------------|
| Intended use | Expiry Date |
| Product Format | Recommended storage conditions |
| Volume | Hazardous Information |

Approved CoA

Signature

Jane Leary

Date

09 mar 2018



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